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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/811,546	03/20/2001	Karl Kolter	51284	9100

26474 7590 06/30/2005

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EXAMINER

SPEAR, JAMES M

ART UNIT PAPER NUMBER

1618

DATE MAILED: 06/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/811,546

Applicant(s)

KOLTER ET AL.

Examiner

James M. Spear

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-19 and 21-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-19 and 21-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

James M. Spear
JAMES M. SPEAR
PRIMARY EXAMINER
AU 1618

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

AS

The finality of the last office action is withdrawn. Prosecution on the merits of this application is reopened on claims 1, 3-19 and 21-24 considered unpatentable for the reasons indicated below:

Following are new grounds of rejection.

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1, 3-19 and 21-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment to claim 1 incorporating the limitation "from greater than" 20 to "less than or equal to" 80 % is considered new matter. The specification only recites concentrations of from 10 to 80 %, preferably from 20 to 60 %. Page 7, lines 25-30. There is no support for claiming from greater than 20 % excluding ranges of the prior art.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 3-19 and 21-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Kolter et al. DE 197 09 663 A1; hereafter US 6,066 334 is relied upon as an English Translation. See Abstract, column 2, lines 23-47, example 1, claims 1 and 4. The reference shows a composition comprised of a binder wherein the binder is a mixture of polyvinyl acetate and polyvinylpyrrolidone in an amount of .5 % to 20 %.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a

background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1, 3-19 and 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kolter et al in view of Ortega US 4,837,032.

8. Kolter et al shows applicants' solid dosage form as explained above.

Kolter et al does not recite delayed release of active agents in the claims.

However Kolter et al shows release of the active agent within a time of from .1 to 1 hour. Claim 1. It is the position of this office that a release rate within a time of 1 hour suggests delayed release. Furthermore Kolter et al recognizes the release properties imparted to the composition in relation to the prior art. Column 4, lines 38-50. It is well known in the art that binders will modify or delay drug release. Ortega is relied on for teaching sustained release dosage forms wherein a polymeric matrix is utilized. Ortega uses polyvinylpyrrolidone and polyvinyl acetate primarily in greater amounts than Kolter et al. Ortega in describing the invention uses terminology such as controlled steady release and extended period of time to describe release

rates of up to 12 hours. Claim 11, column 2, lines 50-62. The prior art clearly shows it is well known in the art to use the particular combination of polymers to modify the release of active agents from oral solid dosage forms. One skilled in the art such as Kolter et al whose examples teach analgesics requiring quick onset of action and Ortega who teaches theophylline, a maintenance drug for asthma, requiring a delayed or sustained release would recognize a need for a particular release rate because of the specific drug used. It would have been obvious to one of ordinary skill in the art to use increased amounts of a polymer combination of polyvinyl acetate and polyvinylpyrrolidone to provide delayed release of an active agent. The motivation being a desire to tailor a dosage form to provide release of a specific active agent at a rate that provides optimum efficacy.

Claims 1, 3-19 and 21-24 are rejected.


Claims 2 and 20 have been canceled.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James M Spear whose telephone

number is 571 272 0605. The examiner can normally be reached on Monday thru Friday from 6:30 AM to 3 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page, can be reached on 571 272 0602. The fax phone number for the organization where this application or proceeding is assigned is 571 273 8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


James M Spear
Primary Examiner
Art Unit 1618

June 27, 2005


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SUPERVISORY PATENT EXAMINER
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